# Supporting recovery in patients with psychosis through care by community-based adult mental health teams (REFOCUS): a multisite, cluster, randomised, controlled trial

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## Summary

**Background** **Mental health policy in many countries is oriented around recovery, but the evidence base for service-level recovery-promotion interventions is lacking.**

**Methods** **We did a cluster, randomised, controlled trial in two National Health Service Trusts in England. REFOCUS is a 1-year team-level intervention targeting staff behaviour to increase focus on values, preferences, strengths, and goals of patients with psychosis, and staff–patient relationships, through coaching and partnership. Between April, 2011, and May, 2012, community-based adult mental health teams were randomly allocated to provide usual treatment plus REFOCUS or usual treatment alone (control). Baseline and 1-year follow-up outcomes were assessed in randomly selected patients. The primary outcome was recovery and was assessed with the Questionnaire about Processes of Recovery (QPR). We also calculated overall service costs. We used multiple imputation to estimate missing data, and the imputation model captured clustering at the team level. Analysis was by intention to treat. This trial is registered, number ISRCTN02507940.**

**Findings** **14 teams were included in the REFOCUS group and 13 in the control group. Outcomes were assessed in 403 patients (88% of the target sample) at baseline and in 297 at 1 year. Mean QPR total scores did not differ between the two groups (REFOCUS group 40·6 [SD 10·1] *vs* control 40·0 [10·2], adjusted difference 0·68, 95% CI –1·7 to 3·1, p=0·58). High team participation was associated with higher staff-rated scores for recovery-promotion behaviour change (adjusted difference –0·4, 95% CI –0·7 to –0·2, p=0·001) and patient-rated QPR interpersonal scores (–1·6, –2·7 to –0·5, p=0·005) at follow-up than low participation. Patients treated in the REFOCUS group incurred £1062 (95% CI –1103 to 3017) lower adjusted costs than those in the control group.**

**Interpretation** **Although the primary endpoint was negative, supporting recovery might, from the staff perspective, improve functioning and reduce needs. Implementation of REFOCUS could increase staff recovery-promotion behaviours and improve patient-rated recovery.**

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## Introduction

An orientation towards supporting personal recovery is national mental health policy in England and Wales,[1] and throughout much of the English-speaking world. This focus on recovery has been reiterated in the UK Chief Medical Officer's report on public mental health.[2] In this context, personal recovery is defined as a way of living a satisfying and hopeful life, including contribution to society, even with any limitations caused by illness.[3] This modern meaning of recovery can be contrasted with the traditional focus of clinical recovery on symptoms and disability. Epidemiological evidence indicates that most people with mental illnesses will achieve clinical recovery in the long term.[4]

Scientific knowledge about interventions to support personal recovery is expanding, with reviews available of, for example, vocational rehabilitation, peer support, and advance directives.[5] Programmes are underway internationally to support recovery-promotion system transformation.[6] Despite this progress, policy is substantially ahead of research and practice. To catch up, new evidence-based interventions will need to be introduced and changes made in staff–patient relationships, treatment (eg, with emerging evidence that psychosocial interventions for psychosis could be effective without pharmacotherapy),[7] and assessment by expanding diversity in outcomes (eg, employment and personal relationships in addition to traditional outcomes, such as symptoms and functioning).[8] Initiatives are needed at all levels within the system, not just the staff–patient level, to achieve changes in organisational culture that will support recovery.

We assessed the usefulness of the REFOCUS team-level intervention to support personal recovery[9] informed by the theory of planned behaviour.[10] This theory proposes that behavioural intent is affected by attitudes, subjective norms, and the perceived degree of behavioural control. Meta-analysis of health research suggests that the theory accounts for over 20% of actual behaviour.[11] The REFOCUS intervention is intended to be suitable for

various diagnoses and all types of community-based adult mental health teams. An international review found that staff can support recovery through what they do with patients (the supporting recovery practice domain) and how they work with patients (the working relationship practice domain).[12] Thus, the intervention targets care content (what) by supporting the use of three working practices, as described in the methods, and care processes (how) through training staff in coaching and giving opportunities for other recovery-promoting relationships. The intervention and assessments are based on the REFOCUS model, which is described in the intervention manual.[9] Following the Medical Research Council framework for complex health interventions,[13] the model specifies the intended causal pathway from intervention, through changes in practice and the patient's experiences, to recovery. We compared outcomes for patients receiving treatment from community-based adult mental health teams, with or without the REFOCUS intervention. We focused on the effects in patients with psychosis, with the aim of providing evidence to inform disorder-specific clinical guidelines. We tested the hypothesis that the REFOCUS intervention would be associated with improved recovery compared with usual care.

## Methods

### Study design and participants

We did a cluster, randomised, controlled trial that involved two mental health National Health Service (NHS) Trusts in England, between April, 2011, and May, 2012. The trial manual[9] and protocol of the study[14] have been previously published. Ethics approval was obtained from the East London Research Ethics Committee. Researchers were trained in administration of all standardised measures, and trial conduct was overseen by a trial steering committee (appendix).

See Online for appendix

As the intervention is at the team level, we used a cluster design, with a cluster being a mental health team (the unit of service delivery in the NHS), to keep contamination to a minimum. Team inclusion criteria were community-based adult mental health teams providing care coordination for adults with the care programme approach,[15] which is a national framework for care coordination and resource allocation in mental health care. Teams were recruited from the South London and Maudsley NHS Foundation Trust (SLaM) in southeast London, and the 2gether NHS Foundation Trust in Gloucestershire. SLaM is the largest mental health trust in the UK and has an annual income of £330 million spent across over 100 sites in urban and suburban settings. It employs 4500 staff in 296 teams and works with 34 128 service users. 2gether is a rural and semi-rural trust that employs 806 staff in 23 adult mental health teams and works with 4301 service users. Potentially eligible teams were identified by service managers, after which researchers discussed participation with the service and team managers and lead clinicians.

Eligible patients were aged 18–65 years, had a primary clinical diagnosis of psychosis (eg, schizophrenia, schizoaffective disorder, or bipolar disorder) with no immediate plans for discharge or transfer, were not currently receiving inpatient care, were not in prison, spoke and understood English, were not participating in any other substantial study, were deemed by their clinicicans to be sufficiently well to participate, and were in regular contact with at least one worker in the mental health team (as judged by the team). Exclusion criteria were being unable to give consent or being unknown to or uncontactable by the service. Each team's clinical records were screened for initial eligibility (age and diagnosis). Clinicians obtained permission from patients to be approached by researchers, who established eligibility. Written informed consent and baseline data were obtained from participants by researchers before randomisation.

Staff inclusion criteria were providing clinical input to a participating team (only one team for staff who were suggested as key informants by patients) and being in regular clinical contact with the participating service user. All staff gave written informed consent and completed baseline assessments before randomisation.

### Randomisation and masking

Teams were allocated equally to usual treatment plus the REFOCUS intervention or to usual treatment alone (control), stratified by allocation wave to the four SLaM boroughs and two 2gether localities to ensure balance. Block randomisation of teams was undertaken by the independent Mental Health and Neuroscience Clinical Trials Unit. For each team, the screened cases of potentially eligible patients were randomly ordered, according to procedures set out by the Mental Health and Neuroscience Clinical Trials Unit, and were recruited in the order of that list. Participating staff, patients, and researchers were aware of allocation status.

### Procedures

All teams were multidisciplinary and provided care coordination under the care programme approach, in which systematic arrangements for assessing health and social needs, formation of a care plan identifying the health and social care needed from various providers, appointment of a key worker to monitor and coordinate care, and regular review of the care plan are important features. Teams allocated to the REFOCUS group received training in the REFOCUS intervention.[9] Briefly, REFOCUS is a 1-year intervention that involves the whole team and takes into account the values of teams and individual staff members (which can be conflicting)[16] recovery-related knowledge, skills and behaviour, and staff–patient relationships. The intervention has behavioural and interpersonal components. The behavioural component comprises three desired behaviours by staff, called working practices. Working practice 1 involves

understanding patients' values and identity beyond being a patient and placing patients' preferences at the centre of planning care. Working practice 2 involves assessing patients' personal and social strengths with a standard approach to identify existing and potential resources on which the patient can build. Working practice 3 involves supporting patients in striving for goals by orienting clinical care around goals valued by the patient. Working practices are fulfilled in the context of the interpersonal component (called recovery-promoting relationships) and includes training staff to use coaching skills in interactions with patients[17] and to start partnership projects, in which staff and patients take on joint non-clinical tasks, with a small resource of £500 for each team.

Implementation of REFOCUS was supported by meetings and training. Intervention briefing meetings about the study were held separately for patients and informal carers and for staff. The following training and support meetings were offered to staff: 12 h (three 4 h sessions) of training in personal recovery provided by two trainers (one with a professional background and one with a service-use background); 16 h (one 8 h and two 4 h sessions) of training in recovery coaching from a coaching trainer, with telephone support and optional booster sessions; six externally facilitated team-manager reflection groups to support culture change; six team reflection groups (three externally facilitated, three not facilitated) to foster experiential learning; and the use of a reflective practice tool in individual supervision.

## Outcomes

The primary outcome was recovery, which was assessed with the Questionnaire about the Process of Recovery (QPR).[18] This measure was deemed appropriate on the basis of a systematic review.[19] QPR is a 22-item patient-rated assessment of recovery, developed from a qualitative study led by service-user researchers.[20] Example items are "I can actively engage with life" and "I am able to develop positive relationships with other people". Each item is rated on a five-point scale from 0 (disagree strongly) to 4 (agree strongly). The initial version comprised two subscales, QPR intrapersonal (17 items with a score range of 0–68) and QPR interpersonal (five items with a score range of 0–20), with higher scores indicating increased recovery. Adequate internal consistency (intrapersonal 0·94 and interpersonal 0·77), construct validity, and test-retest reliability (intrapersonal 0·87 and interpersonal 0·76) were shown.[18] Subsequently, one 15-item questionnaire with a score range of 0–60 (QPR total) was developed that had internal consistency of 0·93 and test-retest reliability of 0·70.[21] Significant correlation was shown between the 15-item QPR and the standard measures of symptoms, hope, and self-esteem.[21] In this study we calculated QPR total, intrapersonal, and interpersonal scores for patients.

To measure the secondary outcomes of hope, quality of life, empowerment, wellbeing, and met and unmet needs in patients, we used, respectively, the Herth Hope Index, Manchester Short Assessment of Quality of Life (MANSA) questionnaire, Mental Health Confidence Scale, Warwick-Edinburgh Mental Well-Being Scale, and Camberwell Assessment of Needs Short Appraisal Schedule-Patient (CANSAS-P). To measure experience (satisfaction and recovery support) in patients, we used the Client Satisfaction Questionnaire and INSPIRE. To measure staff-rated outcomes (met and unmet needs, functioning, and social disability), we used CANSAS-Staff (CANSAS-S), the Global Assessment of Functioning (GAF), and the Health of the Nation Outcome Scale (HoNOS). Researchers rated symptoms with the Brief Psychiatric Rating Scale and service use with the Client Service Receipt Inventory.

For the quantitative elements of assessment, all staff completed measures of their recovery-related knowledge and attitudes with the Recovery Knowledge Inventory (RKI), attitudes towards mental illness with the Mental Illness: Clinicians' Attitudes (MICA) questionnaire, and two non-standardised measures, the Participation Scale and the Recovery Practice Scale. The Participation Scale was used to rate attendance and engagement with personal recovery training, coaching training, and team reflection sessions. The Recovery Practice Scale was used to assess self-rated skills, behavioural intent, and behaviour in relation to coaching, values, strengths, striving to achieve goals, and partnership relationships. Details of all measures are provided in the appendix.

Data were collected by researchers who were trained in all measures. Teams were contacted 4 months before allocation to start collection of baseline data, although most information was collected in the month before allocation. Patients completed questionnaires during meetings with researchers and each identified his or her care coordinator or another appropriate paired professional in the mental health team. Researchers completed the Brief Psychiatric Rating Scale and Client Service Receipt Inventory, while with patients and the identified paired staff were approached and asked to complete CANSAS-S, HoNOS, and GAF separately. Teams were allocated to study groups after all baseline questionnaires were completed. 1 year after randomisation, all assessments were repeated, with staff in the REFOCUS group also completing the Participation Scale. Follow-up data for patients were sought irrespective of any changes in circumstances (eg, team disbanded, discharge, move to a new NHS Trust, imprisonment, or change to inpatient status). Most data were collected within 1 month. Patients were offered £10 for their time after attendance at each assessment, and could be entered into a £50 prize draw. Staff data were collected from the same member of staff where possible, otherwise they were collected from an appropriate alternative team member.

Data recorded on paper forms were transcribed to an electronic database that the researchers were trained to

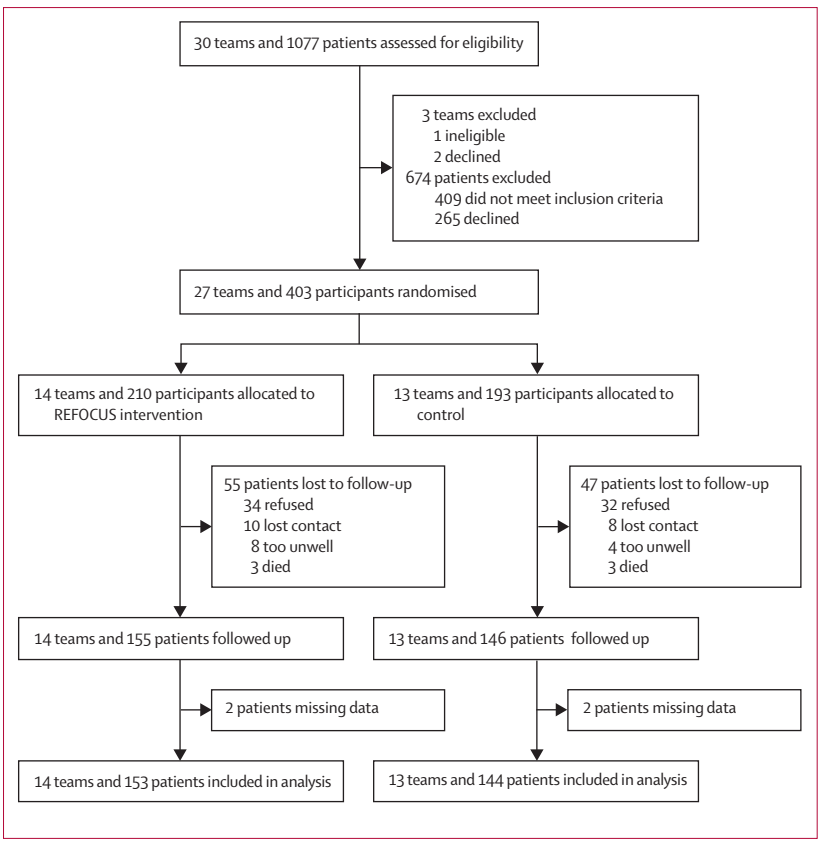


***Figure:*** **Trial profile**

use. A data entry protocol was followed to ensure consistency and data validation rules were applied to reduce transcription errors. All identification numbers were checked to ensure matches between data, and all data flagged as missing were checked manually to confirm. A random 20% sample of patient-rated (QPR, Client Satisfaction Questionnaire, and CANSAS-P) and staff-rated (CANSAS-S, GAF, HoNOS, MICA, RKI, and Recovery Practice Scale) follow-up data were manually checked against paper copies and showed agreement of 99·66% and 99·75%, respectively.

The REFOCUS cost analysis was based on the staff time involved in delivering the intervention combined with the unit costs for those staff members, which were derived from those reported by Curtis[22] and NHS reference costs (appendix). The resulting values were divided by number of cases per team to derive the cost per service user. This approach is conservative because it assumes that the training will only benefit current service users. If it were assumed that future services users could also benefit, the cost would be reduced. Other service use data included contacts with primary and secondary health-care services (including days in hospital) and social care. No imputation was used for loss to follow-up because this occurred for a small number of cases across a wide range of services. To allow calculation of total costs, however, we used a standard economic assessment approach that when a service was used but the number of contacts was not recorded, data were imputed with median values from complete cases.

### Statistical analysis

All analyses were done with Stata (version 11). We calculated that 29 teams (with 17% attrition to 24 teams), 336 patients (15 patients per team with 7% attrition to 14 per team), and an estimated team-level intracluster correlation of 0·05 (a conservative estimate of the similarities of teams),[23] would be sufficient to achieve 80% power to show a medium standardised effect size of 0·4 at $\alpha$=0·05.

Missing data (other than for the six patients who died during follow-up) were estimated with multiple (50) imputations by chained equation (Stata MICE command). The imputation model reflected clustering at team level and, as multiple imputation relies on the assumption that data are missing at random, included baseline outcome measures and covariates to improve the estimation of missing values. Sensitivity analyses showed that the distributions of the imputed items and complete cases were similar, yielded equivalent result patterns, and that analyses based on missing data imputed for outcome measures at baseline and follow-up compared with baseline only were not associated with increased biased estimates.[24]

Analyses of imputed data were done by intention to treat. Regression analysis was used to assess differences between the study groups in primary and secondary outcomes, with adjustment for baseline scores.[25] We did random effects regression analyses with maximum likelihood estimation, using the Stata xtmixed command, to take team-level clustering into account. The model was also adjusted for wave to reflect the stratified design. We used prospective $\alpha$ allocation to correct for type I error inflation due to multiple comparisons.[26] We set the experiment-wise $\alpha$ level at 0·10, the significance level for testing the primary outcome set at 0·05, and $\alpha$=0·004 for each of the secondary outcomes (ie, $\alpha$=0·05/14 secondary outcomes=0·004). Scores screening was implemented before analyses and model diagnostics were done after regression analyses.

Sensitivity analyses were done with adjustment for sociodemographic covariates which could be associated with our outcomes.[27] These covariates, recorded at baseline, were sex, age, years using mental health services, ethnic origin (white British *vs* other), accommodation type (privately owned and rented *vs* other), marital status (single *vs* relationship), and education (higher education *vs* non-higher education). These covariates were entered simultaneously into the regression model to assess whether results were modified.

Finally, we did post-hoc analyses relating to participation. Staff participation data were calculated only for staff who did not move teams and who had baseline and follow-up ratings. To assess whether staff participation at

| | REFOCUS group (n=210) | Control group (n=193) |
|---|---|---|
| **Patients' characteristics** | | |
| Sex | | |
| Male | 131 (63%) | 127 (66%) |
| Female | 78 (37%) | 66 (34%) |
| Ethnicity | | |
| White | 115 (56%) | 95 (49%) |
| Non-white | 92 (44%) | 98 (51%) |
| Accommodation | | |
| Privately owned or rented | 48 (23%) | 22 (12%) |
| Supported | 161 (77%) | 168 (88%) |
| Relationship | | |
| Single | 151 (72%) | 158 (82%) |
| In a relationship | 59 (28%) | 35 (18%) |
| Education | | |
| Secondary | 111 (54%) | 95 (50%) |
| Higher | 96 (46%) | 96 (50%) |
| Age (years) | 44·87 (10·22) | 42·99 (11·56) |
| Use of mental health services (years) | 16·13 (11·49) | 15·52 (10·89) |
| **Patient-rated outcome scores** | | |
| QPR (n=365) | | |
| Total | 38·53 (9·31) | 38·97 (9·10) |
| Intrapersonal | 43·77 (10·18) | 43·95 (10·10) |
| Interpersonal | 13·55 (2·43) | 12·94 (2·67) |
| CANSAS-P | | |
| Met needs (n=390) | 3·98 (3·33) | 3·66 (2·82) |
| Unmet needs (n=390) | 3·54 (3·01) | 3·58 (2·79) |
| HHI (n=362) | 35·25 (4·81) | 35·92 (4·94) |
| MANSA (n=275) | 4·75 (0·97) | 4·60 (0·88) |
| MHCS (n=335) | 65·23 (14·40) | 66·38 (14·63) |
| WEMWBS (n=373) | 47·39 (9·51) | 46·68 (10·36) |
| (Continued from previous page) | | |
| **Patient-rated experience scores** | | |
| CSQ (n=380) | 25·24 (5·25) | 25·51 (5·08) |
| INSPIRE | | |
| Relationship (n=377) | 77·77 (17·55) | 76·76 (14·95) |
| Support (n=396) | 65·41 (21·48) | 59·39 (20·68) |
| **Staff-rated outcome scores** | | |
| BPRS (n=349) | 33·63 (10·13) | 31·90 (9·17) |
| CANSAS-S | | |
| Met needs (n=387) | 5·80 (3·67) | 5·74 (3·52) |
| Unmet needs (n=387) | 3·19 (2·82) | 3·50 (2·79) |
| GAF (n=379) | 64·66 (13·88) | 64·15 (14·84) |
| HoNOS (n=366) | 8·05 (5·08) | 10·45 (6·44) |
| **Process outcome scores** | | |
| RKI | 2·97 (0·38) | 2·94 (0·40) |
| MICA | 30·47 (6·96) | 31·37 (6·96) |
| RPS | | |
| Skills | 2·79 (0·64) | 2·73 (0·66) |
| Behavioural intent | 1·66 (0·34) | 1·68 (0·37) |
| Behaviour | 1·78 (0·78) | 1·74 (0·77) |

(Table 1 continues in next column)

Data are number (%) or mean (SD). QPR=Questionnaire about the Process of Recovery. CANSAS-P=Camberwell Assessment of Needs Short Appraisal Schedule-Patient. HHI=Herth Hope Index. MANSA=Manchester Short Assessment of Quality of Life. MHCS=Mental Health Confidence Scale. WEMWBS=Warwick-Edinburgh Mental Well-Being Scale. CSQ=Client Satisfaction Questionnaire. BPRS=Brief Psychiatric Rating Scale. CANSAS-S=Camberwell Assessment of Needs Short Appraisal Schedule-Staff. GAF=Global Assessment of Functioning. HoNOS=Health of the Nation Outcome Scale. RKI=Recovery Knowledge Inventory. MICA=Mental Illness: Clinicians' Attitudes. RPS=Recovery Practice Scale.

***Table 1*: Baseline sociodemographic and clinical characteristics**

the team level was associated with QPR follow-up scores, adjusted for baseline scores, we extrapolated a measure of team participation by pooling the ratings on the participation scale for staff in each team (α=0·89). We used a median split to dichotomise intervention teams into high or low participation, which allowed the variable team participation (control, low participation, or high participation) to be extrapolated. We used a median split on the participation scale to identify low and high participating staff within the intervention group, allowing extrapolation of a staff participation variable (control, low participation, or high participation). We regressed patients' outcomes (missing data estimated with scale guidelines or prorated where less than 20% of items were missing) by team participation, staff process measures, and staff participation. We used the Stata xtmixed command to account for clustering at the team level. Analyses were adjusted for baseline scores and Trust centre. Costs were calculated by combining service-use data with the unit costs and were compared between the two groups for patients with baseline and follow-up cost data. We used a bootstrapped regression model to correct for potential skewing of data and to control for baseline costs. Costs are reported in 2012/13 UK pounds. This trial is registered, number ISRCTN02507940.

### Role of the funding source

The funder had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

## Results

27 teams (18 from SLaM and nine from 2gether) and 403 patients were randomised (figure, appendix). Teams comprised 13 recovery teams providing long-term support to patients with complex health and social needs (nine in the REFOCUS group and four in the control group), four psychosis teams specialising in work with patients with psychosis and complex needs (two and two), three high-support forensic teams for patients with complex needs and risk issues (two and one), three assertive outreach teams for hard-to-engage patients (all in the control

| | Regression | | Intracluster correlation |
|---|---|---|---|
| | b (p value) | 95% CI | |
| **Patient-rated outcome scores** | | | |
| QPR | | | |
| Total | 0·63 (p=0·55) | −1·41 to 2·67 | 0 |
| Interpersonal | 0·13 (p=0·75) | −0·93 to 0·67 | 0·05 |
| Intrapersonal | 0·49 (p=0·44) | −1·71 to 2·70 | 0 |
| CANSAS-P | | | |
| Met needs | 0·43 (p=0·43) | −0·63 to 1·49 | 0·10 |
| Unmet needs | −0·31 (p=0·41) | −1·04 to 0·42 | 0·03 |
| HHI | 0·65 (p=0·30) | −0·59 to 1·88 | 0·03 |
| MANSA | −0·04 (p=0·73) | −0·27 to 0·19 | 0·01 |
| MHCS | 2·00 (p=0·23) | −1·23 to 5·22 | 0·03 |
| WEMWBS | 0·76 (p=0·51) | −1·50 to 3·01 | 0·01 |
| **Patient-rated experience scores** | | | |
| CSQ | 0·71 (p=0·20) | −0·38 to 1·79 | 0 |
| INSPIRE | | | |
| Support | −2·43 (p=0·41) | −8·22 to 3·36 | 0·01 |
| Relationship | −0·39 (p=0·86) | −4·66 to 3·88 | 0 |
| **Staff-rated outcome scores** | | | |
| BPRS | −1·85 (p=0·15) | −4·37 to 0·66 | 0·12 |
| CANSAS-S | | | |
| Met needs | 0·07 (p=0·91) | −1·29 to 1·16 | 0·13 |
| Unmet needs | −0·80 (p=0·03) | −1·52 to −0·65 | 0·10 |
| GAF | 5·90 (p<0·0001) | 2·61 to 9·18 | 0·01 |
| HoNOS | −1·21 (p=0·07) | −2·53 to 0·10 | 0·04 |

Total number of patients 397 (207 REFOCUS group, 190 controls). QPR=questionnaire about the process of recovery. CANSAS-P=Camberwell Assessment of Needs short appraisal schedule-patient. HHI=Herth Hope index. MANSA=Manchester Short Assessment of Quality of Life. MHCS=Mental Health Confidence Scale. WEMWBS=Warwick-Edinburgh Mental Well-Being Scale. CSQ=Client Satisfaction Questionnaire. BPRS=Brief Psychiatric Rating Scale. CANSAS-S=Camberwell Assessment of Needs Short Appraisal Schedule-Staff. GAF=Global Assessment of Functioning. HoNOS=Health of the Nation Outcome Scale.

***Table 2*: Comparison of outcomes between full imputed groups at follow-up, adjusted for baseline scores and wave**

group), two supported-living teams for patients in supported accommodation (both in the control group), one low-support team for patients with less-complex needs (in the REFOCUS group), and one early-intervention team for patients in the first 3–5 years after psychosis being diagnosed (in the control group).

Baseline characteristics of patients are shown in table 1. Patients in the intervention group were significantly more likely to live in privately owned or rented accommodation, to be in a relationship, and to be unemployed than those in the control group, although significance was lost after Bonferroni adjustment to account for multiple comparisons. The control group had higher social disability scores on HoNOS (p<0·0001), but did not differ significantly from the REFOCUS group for any other characteristics.

14 intervention briefing sessions were run by researchers for patients and carers and 14 for staff. Attendance per meeting ranged from 0 to 25 patients, and from 50% to 80% of staff per team. 41 of the planned 42 personal recovery training sessions were run, with a median attendance of 14·4 (range 8–24) team members in session one, 13·1 (4–21) in session two, and 10·4 (6–15) in session three. All the planned 42 coaching training sessions were run, with attendance of 14·7 (12–21) team members in session one, 12·0 (7–19) in session two, and 11·3 (5–24) in session three. The proportions of staff attending training sessions cannot easily be quantified because high staff turnover rates complicate the denominator, but most staff seem to have attended training.

12 of the intended 36 externally facilitated team reflection groups were run, with median attendance of 10·0 (range 5–21) team members per session. No formal records were kept of the non-facilitated team or team-manager reflection groups, due to limited capacity in the research team, but few, if any, sessions seem to have happened. Reasons for reduced engagement were low team motivation and logistical challenges (eg, difficulties in obtaining cover for whole-team sessions and staff being busy). We had no evidence of supervision reflection forms being used in supervision sessions.

Overall, five of the intended 14 partnership projects were run. These comprised building a website, organising a Christmas party, and providing an information session for a group of patients with SLaM, and an Olympics sports day and a 3-day outward-bound course with 2Gether. Towards the end of the trial, two teams (one in the REFOCUS group and one in the control group) disbanded but follow-up data were obtained from patients and paired staff.

Data were available for 532 staff at baseline, follow-up, or both. Of these, 336 were in the same team at baseline and follow-up, 105 left after baseline, 70 joined before follow-up, and 21 moved between teams (nine to a team in the same study group, eight from the REFOCUS group to the control group, and four from the control group to the REFOCUS group). Six patients (three in the REFOCUS group and three in the control group) died during the study period, all for reasons identified as unrelated to the intervention by their clinicians. These patients were excluded from the analysis. Some adverse events were reported (three deaths in each group) but none was deemed to be due to the intervention.

Missing data were estimated for all but the six patients who died during follow-up. Therefore, at 1-year follow-up, QPR data were available for 275 (69%) of 397 patients (appendix). Missing data across QPR scales was not associated with any sociodemographic covariate and was only associated with CANSAS-P met needs among the clinical measures (patients with complete QPR data had higher scores for met needs at baseline than those with missing data, p=0·02), although the difference became non-significant after adjustment for multiple pairwise comparisons. Data for secondary outcomes were available for 60–91% of patients (appendix).

121 patients in the control group and 134 in the REFOCUS group had complete data. QPR mean scores were stable between baseline and follow-up in the two

| | Number of patients and mean (SE) score | | | Overall | Control *vs* low participation (b, p value [95% CI]) | Control *vs* high participation (b, p value [95% CI]) | Low *vs* high participation (b, p value [95% CI]) |
|---|---|---|---|---|---|---|---|
| | Control | REFOCUS low participation | REFOCUS high participation | | | | |
| QPR | | | | | | | |
| Total | 144, 40·01 (0·59) | 67, 40·74 (1·08) | 74, 41·30 (0·96) | $\chi^2$=1·57*, p=0·46 | 0·74, p=0·55 (–1·70 to 3·18) | 1·29, p=0·26 (–0·94 to 3·53) | –0·56, p=0·73 (–3·77 to 2·66) |
| Interpersonal | 144, 13·54 (0·20) | 67, 12·82 (0·37) | 74, 14·39 (0·33) | $\chi^2$=8·23*, p=0·02 | –0·72, p=0·09 (–1·54 to 0·11) | 0·85, p=0·03 (0·09 to 1·62) | –1·57, p=0·005 (–2·66 to –0·48) |
| Intrapersonal | 144, 45·36 (0·65) | 67, 46·18 (1·18) | 74, 46·58 (1·06) | $\chi^2$=1·23*, p=0·54 | 0·82, p=0·60 (–1·87 to 3·50) | 1·21, p=0·33 (–1·24 to 3·67) | –0·40, p=0·83 (–3·93 to 3·14) |
| GAF | 169, 62·3 (1·07) | 53, 67·1 (2·17) | 82, 69·3 (1·76) | $\chi^2$=14·60*, p=0·0007 | 4·8, p=0.051 (–0·01 to 9·58) | –7·0 p=0·001 (–11·07 to 2·98) | –2·24, p=0·47 (–8·31 to 3·82) |
| HoNOS | 168, 10·1 (0·41) | 59, 7·8 (0·79) | 78, 10·1 (0·67) | $\chi^2$=6·71*, p=0·03 | –2·32, p=0·01 (–4·08 to 0·56) | –0·04, p=0·96 (–1·60 to 1·51) | –2·36, p=0·041 (–4·62 to –0·10) |

QPR=Questionnaire about the Process of Recovery. GAF=Global Assessment of Functioning. HoNOS=Health of the Nation Outcome Scale. *Two degrees of freedom.

***Table 3*: Relation between team-level participation and patient-rated recovery, adjusted for baseline scores**

| | Number of patients and mean (SE) score | | | Overall | Control *vs* low participation (b, p value [95% CI]) | Control *vs* high participation (b, p value [95% CI]) | Low *vs* high participation (b, p value [95% CI]) |
|---|---|---|---|---|---|---|---|
| | Control | REFOCUS low participation | REFOCUS high participation | | | | |
| RKI | 129, 2·92 (0·03) | 72, 2·89 (0·04) | 56, 2·99 (0·04) | $\chi^2$=2·95*, p=0·23 | –0·03, p=0·49 (–0·12 to 0·06) | 0·06, p=0·22 (–0·04 to 0·16) | –0·09, p=0·09 (–0·20 to 0·01) |
| MICA | 131, 30·12 (0·55) | 72, 30·78 (0·73) | 58, 30·65 (0·82) | $\chi^2$=0·59*, p=0·75 | 0·66, p=0·48 (–1·16 to 2·49) | 0·53, p=0·60 (–1·46 to 2·52) | 0·13, p=0·90 (–2·02 to 2·29) |
| RPS | | | | | | | |
| Skills | 114, 2·87 (0·06) | 66, 2·74 (0·08) | 50, 2·95 (0·09) | $\chi^2$=3·49*, p=0·17 | –0·14, p=0·16 (–0·33 to 0·05) | 0·07, p=0·33 (–0·14 to 0·29) | –0·21, p=0·08 (–0·45 to 0·02) |
| Behavioural intent | 114, 1·67 (0·03) | 66, 1·60 (0·04) | 50, 1·68 (0·05) | $\chi^2$=2·24*, p=0·33 | –0·07, p=0·18 (–0·18 to 0·03) | 0·01, p=0·87 (–0·11 to 0·13) | –0·08, p=0·21 (–0·21 to 0·05) |
| Behaviour | 114, 1·80 (0·07) | 66, 1·54 (0·09) | 50, 1·97 (0·10) | $\chi^2$=10·92*, p=0·004 | –0·26, p=0·02 (–0·48 to –0·05) | 0·16, p=0·18 (–0·08 to 0·40) | –0·43, p=0·001 (–0·69 to –0·16) |

RKI=Recovery Knowledge Inventory. MICA=Mental Illness: Clinicians' Attitudes. RPS=Recovery Practice Scale. *Two degrees of freedom.

***Table 4*: Relation between team-level participation and staff-rated knowledge, attitudes, and behaviour, adjusted for baseline scores**

study groups for the total score (control baseline 38·6 [SD 9·5] *vs* follow-up 40·2 [10·3]; intervention 38·5 [9·8] *vs* 40·6 [10·1]), the intrapersonal subscale (control 43·6 [10·6] *vs* 45·5 [10·3]; intervention 43·7[10·6] *vs* 46·1 [11·1]), and the interpersonal subscale (control 13·1 [2·8] *vs* 13·4 [2·7]; intervention 13·6 [2·2] *vs* 13·8 [2·6]).

In the intention-to-treat analysis (397 participants from 27 teams, mean cluster size 15, range 13–17) the QPR total, intrapersonal, and interpersonal scores did not differ between groups at follow-up (table 2). The only differences in secondary outcomes at follow-up were improved scores for GAF and CANSAS-S in the REFOCUS group (table 2), although the latter was non-significant after α adjustment for multiple comparisons.

After adjustment for covariates, effect sizes were weakened for CANSAS-S unmet needs (–0·68, 95% CI –1·42 to –0·006) and GAF (5·32, 2·03 to 8·61; appendix). Patterns were not modified across the other scales. Analysis of complete cases in the intention-to-treat population produced an equivalent pattern of results to that with imputed data (appendix).

We found an effect of team on the QPR interpersonal subscale, Herth Hope Index, MANSA, Mental Health Confidence Scale, Brief Psychiatric Rating Scale, GAF, and CANSAS-P and CANSAS-S scores (table 2). Assessment of residuals revealed some skewing in client satisfaction questionnaire scores, and the results were confirmed with use of bootstrap SE (data not shown).

As part of our post-hoc analysis we explored the association between team participation and follow-up QPR score (average cluster size 11, range 7–14). We found that QPR interpersonal scores adjusted for baseline varied by team participation. Patients receiving care from high-participation teams had significantly higher QPR

| | Service use at baseline | | Service use at follow-up | | Contacts at baseline | | Contacts at follow-up | |
|---|---|---|---|---|---|---|---|---|
| | REFOCUS group (n=139) | Control group (n=127) | REFOCUS group (n=139) | Control group (n=127) | REFOCUS group | Control group | REFOCUS group | Control group |
| General practictioner | 116 (84%) | 98 (77%) | 115 (83%) | 104 (82%) | 3·5 (3·3) | 3·7 (4·0) | 3·2 (3·1) | 3·3 (5·0) |
| Care coordinator | 129 (93%) | 125 (98%) | 113 (81%) | 113 (89%) | 10·4 (7·7) | 14·9 (13·0) | 8·2 (7·1) | 12·1 (12·9) |
| Psychiatrist | 92 (66%) | 77 (61%) | 76 (55%) | 82 (65%) | 2·9 (3·1) | 2·6 (2·8) | 2·3 (2·5) | 2·4 (2·1) |
| Other doctor | 29 (21%) | 27 (21%) | 23 (17%) | 18 (14%) | 2·3 (1·4) | 5·6 (17·0) | 2·6 (2·2) | 2·1 (1·1) |
| Psychologist | 15 (11%) | 21 (17%) | 12 (9%) | 17 (13%) | 8·1 (8·8) | 8·6 (10·0) | 6·0 (7·0) | 10·4 (9·7) |
| Social worker | 14 (10%) | 13 (10%) | 9 (7%) | 3 (2%) | 8·1 (8·5) | 3·9 (3·8) | 6·9 (7·4) | 13·3 (9·5) |
| Nurse | 13 (9%) | 16 (13%) | 20 (14%) | 21 (17%) | 6·6 (6·9) | 19·9 (44·0) | 14·2 (39·1) | 18·0 (37·8) |
| Occupational therapist | 10 (7%) | 13 (10%) | 4 (3%) | 10 (8%) | 7·8 (10·2) | 8·5 (10·5) | 49·5 (87·3) | 5·4 (7·5) |
| Support worker | 30 (22%) | 32 (25%) | 29 (21%) | 32 (25%) | 29·3 (47·1) | 24·4 (21·6) | 45·2 (60·1) | 57·6 (64·2) |
| Vocational worker | 18 (13%) | 8 (6%) | 11 (8%) | 9 (7%) | 5·4 (6·1) | 4·8 (7·5) | 4·1 (4·8) | 29·3 (58·5) |
| Drug and alcohol adviser | 6 (4%) | 5 (4%) | 5 (4%) | 4 (3%) | 4·7 (4·3) | 15·0 (18·9) | 14·0 (12·5) | 18·5 (20·4) |
| Other therapist | 8 (6%) | 11 (9%) | 7 (5%) | 5 (4%) | 13·0 (11·9) | 27·5 (53·4) | 9·7 (8·2) | 16·4 (13·1) |
| Psychiatric health inpatient | 13 (9%) | 10 (8%) | 6 (4%) | 7 (6%) | 30·6 (20·8) | 44·0 (50·8) | 59·7 (75·1) | 67·3 (65·3) |
| Physical health inpatient | 6 (4%) | 6 (5%) | 7 (5%) | 13 (10%) | 3·5 (2·3) | 3·4 (4·0) | 6·0 (7·1) | 7·7 (16·3) |
| Specialist team | 12 (9%) | 16 (13%) | 7 (5%) | 10 (8%) | 14·3 (19·3) | 20·9 (34·3) | 9·6 (9·5) | 13·0 (10·6) |
| Day care | 72 (52%) | 57 (45%) | 53 (38%) | 48 (38%) | 36·0 (61·4) | 28·9 (31·3) | 36·3 (45·1) | 35·7 (42·9) |

Data are number (%) or mean (SD).

*Table 5*: **Service use in the 6 months before baseline and the 6 months before 1-year follow-up**

interpersonal scores at follow-up than did those receiving care from low-participation teams (table 3). The intracluster correlation coefficient was 0 for all QPR scales. High-participation teams also had better results in two secondary outcomes, HoNOS (although this became non-significant after Bonferroni adjustment) and GAF (table 3). No other effect on secondary outcomes was found.

To understand why recovery-supporting relationships might be improved in teams that had higher participation, we investigated staff changes in recovery knowledge (average cluster size 10, range 4–18), attitudes towards mental illness (average cluster size 10, range 5–17), and self-rated adherence (average cluster size 9, range 4–16; table 4). The intracluster correlation coefficient was 0 for all measures. Participation level by staff was not associated with adjusted follow-up scores on MICA and RKI. High staff participation, however, was associated with significantly higher scores for self-rated recovery-promotion behaviour than less participation (table 4).

Service use in the 6 months before baseline and the 6 months before 1-year follow-up was analysed for a subsample of 266 patients with available data (table 5). Contact with general practitioners and care coordinators was substantial. The intensity of the use of some services at baseline and follow-up varied notably. For example, the number of contacts with occupational therapists rose from eight to 50 in the REFOCUS group, but the number of patients in this category was small. Around two-thirds of patients had contact with psychiatrists at baseline, but this fell slightly to 55% for the REFOCUS group by follow-up. Around a quarter of patients in both groups had contact with support workers during each period. At baseline around half of all patients had day-care contact, but the proportion fell to 38% for both groups by follow-up.

The mean overall intervention cost was £120 (appendix), but this varied from £22 to £357. The most expensive service was psychiatric inpatient care even though it was used by relatively few participants (4% in the REFOCUS group and 6% in the control group). Total service-use costs were lower for patients in the REFOCUS group than in the control group, at baseline (£2997 *vs* £3754) and follow-up (£2752 *vs* £3853). After adjustment for baseline costs, the cost difference between the REFOCUS and control groups was £1062 (95% CI –1103 to 3017) in favour of the intervention, but the difference was not significant. Service costs were on average £657 less for patients receiving care from high-participation teams in the REFOCUS group than those for patients receiving care from low-participation teams in the REFOCUS group (95% CI –1555 to 4783), but this difference was also not significant. Owing to the non-significant differences in costs and the primary outcome, further cost-effectiveness analyses were not done.

## Discussion

In 27 community-based adult mental health teams in two NHS Trusts in England, we found no significant effect of the REFOCUS intervention on recovery in patients with psychosis compared with usual treatment. Most secondary outcomes did not differ, with the exceptions of improved functioning (which remained significant after adjustment for multiple testing) and staff-rated unmet needs (which became non-significant after adjustment) in the REFOCUS group. Although we found no evidence

of changes in staff knowledge, skills, or attitudes, scores for self-reported recovery-promotion behaviour were higher for staff in high-participation teams than for those in low-participation teams. Consistent with this finding, patients receiving care from high-participation REFOCUS teams had higher scores on the QPR interpersonal subscale than those receiving care from low-participation REFOCUS teams. Finally, the REFOCUS intervention was associated with reduced care costs, although the difference was not significant.

We offer several explanations for the lack of improvement in the primary outcome. First, and the explanation we favour, is that the intervention was inadequately implemented. Staff participation (ie, physical presence and full engagement in training) was self-rated by staff who were aware of study group allocation because blinding was not possible in this study. Team members might, therefore, have been susceptible to social desirability bias, leading to rating themselves as more engaged than was actually the case. The bias, however, might be slight, because there is no obvious reason why it would not affect all staff across the REFOCUS group, leading to inflation rather than bias. Additionally, recovery was rated by patients. Despite the possibility of bias, higher participation was associated with an increase in staff-reported recovery-promotion behaviours and patient-reported recovery in the QPR interpersonal subscale. The qualitative assessment of process (experiences of staff)[28] showed that implementation barriers occurred at the individual, team, and organisation levels. Implementation of treatment guidelines within specialist mental health services is frequently poor,[29] and faces three translational hindrances: adoption in principle, early implementation, and persistence of implementation.[30] Although policy supports the implementation of recovery-promotion interventions (adoption in principle), early implementation will not necessarily follow. Broader implementation strategies are needed, including leadership and an organisational culture.[31]

Second, the REFOCUS intervention might be ineffective in its primary aim of improving personal recovery within the 1-year time frame of the intervention. Indeed, the original REFOCUS intervention was 18 months and was shortened due to difficulty in recruiting patients. The patients in this study had been using mental health services, on average, for more than 15 years, which suggests settled staff–patient relationships. Other studies have shown that trusting relationships between patients and staff can take longer to form than is available with short-term interventions.[32] Future research to assess the REFOCUS intervention with an inception cohort of new referrals might be useful to investigate the effects in less-established staff–patient relationships. Similarly, comparison between different groups of workers (eg, multidisciplinary versus single-discipline teams or teams with and without peer support workers) would enable assessment of contamination at the level of staff and and of interaction between worker roles and implementation.

Third, the existing practice of staff in the control group might already have promoted recovery, as, despite the staff in the control group receiving no formal REFOCUS training and the intervention manual being available online, we found no difference in primary outcome between study groups and little evidence of contamination due to staff movement. Many staff in SLaM teams in both study groups would have previously had some recovery training[33] and, therefore, sustained changes in the control group cannot be excluded. Nevertheless, the recovery orientation of participating teams, as measured by RKI (control mean 2·94, intervention mean 2·97), was lower than the mean RKI score of 3·94 found in an Australian study,[34] which suggests there was not a high recovery orientation at baseline.

Finally, although the choice of endpoint assessment was based on recommendations from a systematic review,[19] the QPR has not previously been used as a primary outcome in a trial, and its sensitivity to change has not been fully established. This measure might, therefore, have been insufficiently responsive to detect change. Assessment of the process of recovery with the outcome-oriented methods of evidence-based medicine seems to be intrinsically problematic and more sociological approaches are needed.[35] A qualitative assessment of the experience of patients in this study showed that effective implementation was associated with positive changes in process (more open and collaborative relationships with staff), hope, and empowerment (to be published later), which highlights the challenges of measuring the effects of complex interventions. As a minimum, further psychometric assessment of QPR and other candidate recovery measures is indicated.

In relation to the protocol,[14] this report addresses the first objective of assessing intervention effectiveness. The main protocol deviation was that efforts to estimate the degree of masking for researchers at follow-up were abandoned when it became clear they could not be kept unaware of team allocation status. Validation of the REFOCUS model is addressed in published[36] and submitted process evaluation papers, optimisation of trial parameters is addressed in this report and a revised REFOCUS intervention manual,[37] and the relation between clinical and recovery outcomes is addressed in a report to be published later.

This study has several strengths. The intervention is theory based and the mixed methods for assessment in routine clinical settings across two sites included a range of quantitative and qualitative approaches to investigate adherence, intermediate processes, and outcomes. The clinical population is representative of patients seen in the real world, although the inclusion criterion of clinical judgment about patients being well enough to participate (to allow consideration of the full range of reasons why being approached to participate

### *Panel*: Research in context

#### Systematic review

REFOCUS is a team-level intervention aimed at improving mental health service support for patients' recovery.[9] Development of the REFOCUS intervention was informed by primary research and secondary systematic reviews done to address knowledge gaps. To understand how recovery is supported, we did an inductive, semantic-level, thematic analysis of 30 international documents describing best recovery-promoting practice, which identified four practice domains.[12] The REFOCUS intervention targets the supporting recovery and working relationships practice domains, and does not target the promoting citizenship and organisational commitment practice domains. To identify recovery processes to target with this intervention, we did a systematic review. We searched the AMED, BNI, Embase, Medline, PsycINFO, SSP, CINAHL, IBSS, ASSIA, BHI, sociological abstracts, and SSA databases for articles published from inception to 2009, manually searched three journals, and searched other web-based sources.[38] We used the search terms ("mental health" OR "mental illness$" OR "mental disorder" OR "mental disease" OR "mental problem" OR "psychol$ health" OR "psychol$ illness$" OR "psychol$ disorder" OR "psychol$ problem" OR "psychiatr$ health", OR "psychiatr$ illness$" OR "psychiatr$ disorder" OR "psychiatr$ problem") AND "recover$" AND ("theor$" OR "framework" OR "model" OR "dimension" OR "paradigm" OR "concept$" OR "theme$" OR "stages" OR "processes"). Additional search parameters were English language and either secondary research synthesising the available literature or primary research involving quantitative or qualitative data based on at least three participants. After rating the quality of retrieved articles with established tools, we used narrative synthesis to identify the recovery processes of the connectedness, hope, identity, meaning, and empowerment (CHIME) framework. The CHIME framework was subsequently validated with current service users[39] and across different cultures.[40] To identify the best measure to use in strengths assessment (working practice 2), we systematically reviewed measures of strengths.[41] To identify the optimum primary outcome we systematically reviewed measures of recovery.[19] To inform the development of the new INSPIRE measure[42] we systematically reviewed measures of recovery support.[43] To understand staff perspectives, we developed a grounded theory of staff experiences of supporting recovery.[16] To maximise the feasibility of the intervention, we developed a new measure of feasibility based on implementation science research[36] and an understanding of social effects on recovery.[44] We used expert consultation with patients, carers, staff, and researchers (n=56) to develop the REFOCUS intervention, the REFOCUS model,[9] and the choice of secondary outcomes in the REFOCUS trial.[14] The full theory base and development of the REFOCUS intervention are described elsewhere.[45]

#### Interpretation

We assessed whether implementation of REFOCUS affected staff-rated and patient-rated outcomes in comparison with routine mental health care provided to patients with psychosis. We found no significant effect on the primary outcome of recovery and, of the secondary outcomes, functioning (which remained significant after adjustment for multiple testing) and staff-rated unmet needs (which became non-significant after adjustment) were improved in the REFOCUS group. The most likely explanation for the absence of improvement in recovery is inadequate implementation, because higher staff participation led to higher scores for staff-rated recovery-promoting behaviour and patient-rated interpersonal aspects of recovery than lower participation. Our findings indicate that attention needs to be paid to the organisational commitment practice domain to ensure that support of recovery is organisationally viewed as core business rather than an additional task for mental health services.

might not be appropriate) and the good social functioning indicated by GAF and HoNOS scores might have led to the most disabled people not having participated. The full range of adult mental health teams typically provided in NHS Trusts was included, which maximises representativeness.

A limitation of the study is the absence of a pilot study to inform implementation, which might have identified in advance the challenges presented by practice changes, such as high staff turnover within teams with low morale due to reorganisation within the NHS Trusts. Application of a structured assessment of feasibility[36] indicated that the intervention involves several implementation barriers, including staff training, complexity, human resources, and staff time. We identified organisational leadership and stability plus readiness to change at team level as predictors of implementation,[28] which could provide criteria for inclusion of high-implementing teams in future evaluations. A second limitation is the recruitment shortfall. The analysable sample comprised 297 patients, compared with the target of 336, which was due mainly to a higher attrition rate (26%) than anticipated at follow-up. 88% recruitment could mean that the study was underpowered to detect differences between study groups. Third, the design did not include analyses stratified by team type, which raises the possibility of differential implementation. The relation between team type and outcome was not analysed in this study because of the uneven allocation and because categories were derived from team names and, therefore, might have overlapped. Future trials might more formally establish team types and use either a homogeneous sample or stratify the analysis by team type.

This study contributes to the wider context (panel), and has several clinical implications. From the staff perspective, efforts to support recovery could lead to improved functioning and might also reduce unmet needs for people with psychosis (although not from the patient's perspective). Conversations between staff and patients about values, treatment preferences, and strengths might translate over time into changes in functioning and assessed need. The differences we found in this study between groups do not seem to have been mediated through changes in the recovery variables studied, which suggests a complex relation between these variables. If the positive effect of high participation teams is not due to staff bias in rating implementation, the REFOCUS intervention has the potential to be an effective recovery-promotion intervention if implementation barriers can be addressed. At the societal level, antistigma campaigns improve attainment of valued social roles.[46] Within mental health services, the challenge might be to embed in organisational culture an expectation of partnership-based staff–patient relationships and to focus on the values and treatment preferences, strengths, and goals of patients. Fully supporting recovery, therefore, might require interventions across the whole mental health service, including the patient as an active partner and involving a combination of evidence-based patient-level interventions,[5] team-level interventions, such as REFOCUS, and organisational transformation approaches.[47]

**Contributors**
MS was the principal investigator, ML the programme coordinator, and RM the site lead. VB, EC, CLB, GW and JW contributed to design and data collection. PM and FP led the data analysis. All authors made a substantial contribution to the drafting of the paper, revising it critically for important intellectual content, and gave final approval of the version to be published.

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